# Complete Summary

## GUIDELINE TITLE

Prevention of fecal and urinary incontinence in adults.

## BIBLIOGRAPHIC SOURCE(S)

Landefeld CS, Bowers BJ, Feld AD, Hartmann KE, Hoffman E, Ingber MJ, King JT Jr, McDougal WS, Nelson H, Orav EJ, Pignone M, Richardson LH, Rohrbaugh RM, Siebens HC, Trock BJ. National Institutes of Health state-of-the-science conference statement: prevention of fecal and urinary incontinence in adults. Ann Intern Med 2008 Mar 18;148(6):449-58. PubMed

## GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

- Urinary incontinence
- Fecal incontinence

### GUIDELINE CATEGORY

Prevention
Risk Assessment

### CLINICAL SPECIALTY

Family Practice
Gastroenterology
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine
Urology

## INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Patients
Physician Assistants
Physicians

## GUIDELINE OBJECTIVE(S)

To provide researchers, health care providers, patients, and the general public with an objective assessment of available data on preventing fecal and urinary incontinence and detecting persons at risk for and persons with untreated incontinence

**Note**: The treatment of incontinence with surgery or drugs was beyond the scope of the guideline.

## TARGET POPULATION

Adults in long-term care settings and in the community at risk for and with incontinence

## INTERVENTIONS AND PRACTICES CONSIDERED

### Prevention/Risk Assessment

1. Assessment of risk factors for incontinence
2. Patient education to promote risk awareness
3. Lifestyle changes such as weight loss and exercise
4. Pelvic floor muscle training and biofeedback
5. Treatment of comorbid conditions

## MAJOR OUTCOMES CONSIDERED

- Prevalence, incidence, and natural history of fecal and urinary incontinence in the community and long-term care settings
- Burden of illness and impact of fecal and urinary incontinence on the individual and society

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

**Note from the National Guideline Clearinghouse (NGC)**: A systematic review of the literature was prepared by the Minnesota Evidence-based Practice Center (EPC) for the Agency for Healthcare Research and Quality (AHRQ) for use by the National Institutes of Health (NIH) (see the "Availability of Companion Documents" field).

#### Search Strategy

Studies were sought from a wide variety of sources, including MEDLINE® via PubMed®, CINAHL, Cochrane databases, and manual searches of reference lists from systematic reviews and the proceeding of the International Continence Society (ICS). The search strategies are described in Appendix B of the Evidence Report (see the "Availability of Companion Documents" field). Excluded references are shown in Appendix C of the Evidence Report. All work was conducted under the guidance of a Technical Expert Panel (TEP), whose members are identified in Appendix D of the Evidence Report (see the "Availability of Companion Documents" field).

#### Eligibility

Three investigators independently decided on the eligibility of the studies according to recommendations from the Cochrane manual for systematic reviews. The algorithm to define eligibility of the studies was developed for each research question (refer to Appendix A of the Evidence Report [see the "Availability of Companion Documents" field]). EPC staff reviewed abstracts to exclude secondary data analysis, reviews, letters, comments, and case reports. Then they confirmed eligible target populations of adults in community and long-term care (LTC) settings. The full texts of the original epidemiologic studies published in English after 1989 were examined to include studies with eligible outcomes defined as prevalence and incidence of incontinence, absolute and adjusted relative risk of incidence, and progression of urinary, fecal, and combined incontinence (operational definitions in Appendix A of the Evidence Report [see the "Availability of Companion Documents" field]). A list of risk factors for urinary incontinence (UI) and fecal incontinence (FI) for Question 2 was also developed (operational definitions of known risk factors of UI and FI in Appendix A of the Evidence Report). For Question 3, studies were included that examined the effects of clinical interventions (operational definitions of clinical interventions for the primary and secondary prevention of incontinence in Appendix A of the Evidence Report). For Question 4, EPC staff included studies that evaluated different strategies to detect patients with incontinence and persons at risk. Then studies

that did not test the associative hypotheses and did not provide adequate information on tested hypotheses (e.g., least square means, relative risk) were excluded.

Finally, eligible levels of evidence for each research question were confirmed. The following inclusion criteria were applied to select articles for full review: For questions of prevalence and risk factors of incontinence in large population-based cross-sectional analyses and cohort studies, large cross-sectional analyses and cohorts in LTC settings, case-control studies with randomly selected controls and case series with more than 100 subjects were selected. For the question on clinical interventions to reduce the risk of UI and FI, EPC staff selected randomized controlled clinical trials and multicenter nonrandomized clinical trials (fecal and combined incontinence). For the question on strategies to detect incontinence, randomized controlled clinical trials, multicenter controlled clinical trials, large (>100 subjects) observational studies, and case-control studies with >10 cases that reported sensitivity, specificity, and reliability of different diagnostic methods were selected.

The exclusion criteria included the following:

- Studies with target population as children and adolescents
- Studies with no information relevant to incidence and progression of incontinence
- Studies that examined the distribution of different types of incontinence among incontinent patients (all incontinent in denominator)
- Studies that evaluated the association between incontinence as independent variables in association with other patient outcomes
- Case series with small numbers of cases and no control comparison
- Studies that reported absolute values of the diagnostic tests in incontinent patients
- Studies that did not report true and false positive and negative cases of diagnostic tests
- Observational studies and nonrandomized clinical trials that examined treatments in incontinent patients and short term (less than 1 year of follow-up) drug trials that did not report continence rates

## NUMBER OF SOURCE DOCUMENTS

A total of 1,077 studies were eligible for review.

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

### Levels of Evidence

**I**: Properly designed randomized controlled trial

**II-2A**: Well-designed cohort (prospective) study with concurrent controls and multivariate analysis of the associations

**II-2B**: Well-designed cohort (prospective) study with historical controls and multivariate analysis of the associations

**II-2C**: Well-designed cohort (retrospective) study with concurrent controls and multivariate analysis of the associations

**II-3**: Well-designed case controlled (retrospective) study and multivariate analysis of the associations

**III**: Large differences from comparisons between times and/or places with or without interventions (cross-sectional comparisons)

## METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

**Note from the National Guideline Clearinghouse (NGC)**: A systematic review of the literature was prepared by the Minnesota Evidence-based Practice Center (EPC) for the Agency for Healthcare Research and Quality (AHRQ) for use by the National Institutes of Health (NIH) (see the "Availability of Companion Documents" field).

### Quality Assessment and Rating the Body of Evidence

Study quality was analyzed using the following criteria: subject selection, length and loss of follow-up, adjustment for confounding factors in observational studies and intention to treat principle in clinical trials, masking the treatment status, randomization scheme and adequacy, allocation concealment, and justification of sample sizes in randomized controlled trials (RCTs).

The level of evidence for all studies was estimated using a subset of the U.S. Preventive Services Task Force criteria (see the "Rating Scheme for the Strength of the Evidence" field).

For all questions, evidence tables were developed identifying the purpose of the study, sample, design, independent and dependent variables, and findings. For Questions 1, 2, and 3, incidence and prevalence cases of incontinence, relative risk of incontinence in categories of risk factors and clinical interventions, and outcomes level to assess severity and progression of incontinence for treatment differences were abstracted. Baseline data were compared in different studies to test differences in the target population and unusual patterns in the data. Standard deviations, regression coefficients, and 95 percent confidence interval (CI) were calculated from reported means, standard errors, and sample size. The

protocol for the meta-analyses was created according to recommendations for meta-analysis of randomized controlled trials: the QUOROM statement.

**Data Extraction**

Evaluations of the studies and data extraction were performed manually and independently by three researchers. The data abstraction forms are shown in Appendix E of the Evidence Report (see the "Availability of Companion Documents" field). Errors in data extractions were assessed by a comparison with the established ranges for each variable and the data charts with the original articles. Any discrepancies were detected and discussed. Patient populations were classified as community and long-term care (LTC) settings. Adjustments for patient age, race, gender, comorbidities, socioeconomic status, provider characteristics, and clustering of patients and providers were extracted from the studies. The details on extracted variables are presented in the analytic framework in Appendix A of the Evidence Report (see the "Availability of Companion Documents" field).

**Data Synthesis**

For Questions 1 and 2, results of individual studies (expressed as crude and adjusted for confounding factors) were summarized in evidence tables to analyze differences in incontinence in categories by subject age, race, ethnicity, residency, and risk factors.

*Definitions of Incontinence*

Urinary, fecal, and combined incontinence were analyzed separately. EPC staff used the definitions of signs and symptoms of urinary incontinence (UI) promoted by the International Continence Society (ICS) (refer to Appendix A of the Evidence Report [see the "Availability of Companion Documents" field]) including mixed, stress, and urge incontinence. Anal incontinence (AI) was defined as involuntary loss of flatus, liquid, or solid stool. In the text, the term fecal incontinence (FI) was used and in the tables, the operational definitions of anal (flatus and fecal), FI, solid, or liquid incontinence, or its combinations were clarified. Continence was defined as self-reported absence of involuntary urine or feces loss. Combined incontinence was defined as a combination of urine and fecal incontinence. Frequency of UI or FI was abstracted as daily, weekly, or monthly episodes of urine leakage or feces loss. Severity of UI was defined using the objectively measured urine loss in pad weight tests or self-reported pad use. Severity of FI was defined as self-reported amount of feces loss and pad use. Wet status in nursing home residents was analyzed to define severity of incontinence and effects of the treatments.

*Definitions of Outcomes*

EPC staff defined prevalence of incontinence as the probability of experiencing incontinence within a defined population and at a defined time point. True population incidence was defined as newly diagnosed cases of incontinence that developed annually in the target population. True population incidence estimates were derived from large population-based surveys. However, for Question 3 incidence was defined as the probability of developing incontinence under study

after active and control interventions during time of follow-up. Reported incontinence was defined as the prevalence of total incontinence or episodes of different types of incontinence when the authors did not access continence status as baseline or did not exclude prevalence cases from overall estimation.

The absolute risk of incontinence among patients with rare risk factors was compared to the general population when no other evidence was available to estimate the adjusted relative risk (RR).

For Question 3, RR and 95 percent CIs and differences in outcomes were calculated.

Patient Outcomes (Clinical Events)

EPC staff report both incidence and progression of incontinence as they were used by the authors of the original studies and with calculated rates of cure, improvement, and progression for purposes of comparison:

- The number of patients that developed newly diagnosed incontinence (incidence cases) or the number of incontinent patients after active and control interventions (prevalence cases)
- The number of patients cured by the clinical interventions
- The number of patients with improved continence
- The number of patients with progression defined as failure to cure or improve and increase in frequency and severity of incontinence

Relative risk/odds ratio of developing incontinence was analyzed in the studies that reported incident cases. Relative risk/odds ratio of incontinence was analyzed in the studies that reported prevalence cases. Relative benefit of continence was defined as the likelihood of continence in patients after active treatment relative to those after control interventions. Relative benefit of improvement was defined as a likelihood of improved incontinence in patients after active treatment relative to those after control interventions. Relative risk of progression of incontinence was defined as the likelihood of increasing frequency and severity of incontinence and failure to cure/improve incontinence in patients after active treatment relative to those after control interventions.

Continence was analyzed separately from improvement in incontinence because continence is the most clinically desirable patient outcome and is well defined, whereas improvement can include substantial differences in definitions and changing perceptions of qualitative and quantitative parameters of improvement. Such conservative approaches were used to generate precise estimates of the effectiveness.

Continuous Outcomes (Surrogates)

*Subjective continuous outcomes* were defined as the number of incontinent episodes, use of supplies, and scores from validated scales to analyze the quality of life with incontinence. *Objective continuous outcomes* were defined as the results of objective tests to measure the severity of incontinence.

Pooling criteria included the same operational definitions of incontinence outcomes and the same risk factors or clinical interventions. Homogeneity in clinical interventions was analyzed comparing published information on behavioral, instrumental (devices), pharmacological, and surgical treatments. Meta-analysis was used to assess the consistency of the association between treatments and incontinence outcomes with random effects models. The analyses were conducted separately for symptoms and signs of incontinence. Assumptions underlying meta-analysis included valid measurements of continence status and similarity in study and target populations.

Refer to Chapter 2, "Methods" in the Evidence Report (see the "Availability of Companion Documents" field) for more information.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The National Institute of Diabetes and Digestive and Kidney Diseases and the Office of Medical Applications of Research of the National Institutes of Health convened a State-of-the-Science Conference from 10 to 12 December 2007 to assess the available scientific evidence relevant to the following questions:

1. What are the prevalence, incidence, and natural history of fecal and urinary incontinence in the community and long-term care settings?
2. What are the burden of illness and impact of fecal and urinary incontinence on the individual and society?
3. What are the risk factors for fecal and urinary incontinence?
4. What can be done to prevent fecal and urinary incontinence?
5. What are the strategies to improve the identification of persons at risk and patients who have fecal and urinary incontinence?
6. What are the research priorities in reducing the burden of illness in these conditions?

At the conference, invited speakers presented information pertinent to these questions, and a systematic literature review prepared under contract with the Agency for Healthcare Research and Quality (AHRQ) (www.ahrq.gov/clinic/tp/fuiadtp.htm; see "Availability of Companion Documents" field) was summarized. Conference attendees provided both oral and written statements in response to the key questions. The panel members weighed all of this evidence as they addressed the conference questions.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

The guideline developers reviewed published cost analyses.

## METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

Fecal incontinence and urinary incontinence will affect more than one fourth of all U.S. adults during their lives. The natural history of fecal incontinence is unknown, and the natural history of urinary incontinence over several years is not well described.

Fecal incontinence and urinary incontinence often have serious effects on the lives of the many individuals who have physical discomfort, embarrassment, stigma, and social isolation and on family members, caregivers, and society. Financial costs are substantial and may be underestimated because of underreporting.

Routine episiotomy is the most easily preventable risk factor for fecal incontinence. Risk factors for both fecal and urinary incontinence include female sex, older age, and neurologic disease (including stroke). Increased body mass, decreased physical activity, depression, and diabetes may also increase risk.

Pelvic floor muscle training and biofeedback are effective in preventing and reversing fecal and urinary incontinence in women for the first year after giving birth, and these approaches may also prevent or reduce urinary incontinence in older women and in men undergoing prostate surgery. Fecal and urinary incontinence may be prevented by lifestyle changes, such as weight loss and exercise.

Efforts to raise public awareness of incontinence and the benefits of prevention and management should aim to eliminate stigma, promote disclosure and care-seeking, and reduce suffering. Organized approaches to improving clinical detection of fecal and urinary incontinence are needed and require rigorous evaluation.

To reduce the suffering and burden of fecal and urinary incontinence, research is needed to establish underlying mechanisms, describe a classification system, determine natural history, classify persons according to their future risk for fecal or urinary incontinence, design interventions targeted to specific population groups, determine the effects of these interventions, and guide public policy.

## CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate prevention of urinary and fecal incontinence

### POTENTIAL HARMS

Not stated

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

This statement is an independent report of the panel and is not a policy statement of the National Institutes of Health or the U.S. government.

**Limitations in Finding Risk Factors of Incontinence**

- Ability to find risk factors is limited by the ways that studies were designed and analyzed. The most important limitation is that most existing studies of fecal and urinary incontinence use a cross-sectional design that allows to examine associations with incontinence but not cause. One cannot be sure that the associated factor comes before the occurrence of incontinence or determine whether it is the cause of the incontinence and therefore whether changing the associated factor will reduce or eliminate the incontinence. Studies in which individuals are followed and measured repeatedly over long periods would be necessary to identify true risk factors. Such studies are much more difficult to carry out and appear rarely in the incontinence literature.
- Also of critical importance is the lack of commonly accepted and validated definitions of occurrence for both fecal and urinary incontinence. Because current studies of urinary incontinence use definitions of occurrence that range from minor (a few drops of urine) to major (frequent incontinence that limits daily function) impairment, the size of a risk factor's effect, and even the investigator's ability to establish an effect, varies greatly from study to study. Similar inconsistency exists in the definitions of fecal incontinence.

Refer to the original guideline document for more information.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Landefeld CS, Bowers BJ, Feld AD, Hartmann KE, Hoffman E, Ingber MJ, King JT Jr, McDougal WS, Nelson H, Orav EJ, Pignone M, Richardson LH, Rohrbaugh RM, Siebens HC, Trock BJ. National Institutes of Health state-of-the-science conference statement: prevention of fecal and urinary incontinence in adults. Ann Intern Med 2008 Mar 18;148(6):449-58. PubMed

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2008 Mar 18

### GUIDELINE DEVELOPER(S)

National Institutes of Health (NIH) State-of-the-Science Panel - Independent Expert Panel

### SOURCE(S) OF FUNDING

United States Government

### GUIDELINE COMMITTEE

National Institutes of Health (NIH) State-of-the-Science Panel

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

*Primary Authors*: C. Seth Landefeld, MD; Barbara J. Bowers, PhD, RN; Andrew D. Feld, MD, JD; Katherine E. Hartmann, MD, PhD; Eileen Hoffman, MD; Melvin J. Ingber, PhD; Joseph T. King, Jr., MD, MSCE; W. Scott McDougal, MD; Heidi Nelson, MD; Endel John Orav, PhD; Michael Pignone, MD, MPH; Lisa H. Richardson; Robert M. Rohrbaugh, MD; Hilary C. Siebens, MD; and Bruce J. Trock, PhD

*Panel Members*: C. Seth Landefeld, MD (*Panel and Conference Chair*), University of California, San Francisco, and San Francisco Veterans Affairs Medical Center, San Francisco, California; Barbara J. Bowers, PhD, RN, University of Wisconsin–Madison School of Nursing, Madison, Wisconsin; Andrew D. Feld, MD, JD, University of Washington and Group Health Cooperative, Seattle, and Rockwood Clinic, Spokane, Washington; Katherine E. Hartmann, MD, PhD, Vanderbilt Institute for Medicine and Public Health, Nashville, Tennessee; Eileen Hoffman, MD, New York University School of Medicine, New York, New York; Melvin J. Ingber, PhD, RTI International, Washington, D.C.; Joseph T. King Jr., MD, Veterans Affairs Connecticut Healthcare System and Yale University School of Medicine, New Haven, Connecticut; W. Scott McDougal, MD, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts; Heidi Nelson, MD, Mayo Medical School, Rochester, Minnesota; Endel John Orav, PhD, Brigham and Women's Hospital, Boston, Massachusetts; Michael Pignone, MD, MPH, University of North Carolina Hospital, Chapel Hill, North Carolina; Lisa H. Richardson, Crohn's and Colitis Foundation of America, Houston, Texas; Robert M. Rohrbaugh, MD, Veterans Affairs Connecticut Healthcare System, West Haven, Connecticut; Hilary C. Siebens, MD, University of Virginia, Charlottesville, Virginia; Bruce J. Trock, PhD, The Johns Hopkins University School of Medicine, Baltimore, Maryland

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

None disclosed

## GUIDELINE STATUS

This is the current release of the guideline.

## GUIDELINE AVAILABILITY

Electronic copies: Available from the National Institutes of Health (NIH) Consensus Development Program Web site.

Print copies: Available from the NIH Consensus Development Program Information Center, PO Box 2577, Kensington, MD 20891; Toll free phone (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); autofax (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); e-mail: consensus_statements@mail.nih.gov.

## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Prevention of fecal and urinary incontinence in adults. Evidence Report/Technology Assessment. AHRQ Publication No. 08-E0. Rockville, MD: Agency for Healthcare Research and Quality. 2007 Dec. Available from the AHRQ Web site.

### PATIENT RESOURCES

None available

### NGC STATUS

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Date Modified: 2/23/2009